IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and UCB PHARMA GMBH,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 13-1110 (GMS)
	)	**CONSOLIDATED**
ALKEM LABORATORIES LTD., *et al.*,	)	
	)	
Defendants.	)	

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Pfizer Inc. and UCB Pharma GmbH

OF COUNSEL:

Dimitrios T. Drivas
Jeffrey J. Oelke
James S. Trainor, Jr.
Robert Counihan
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200

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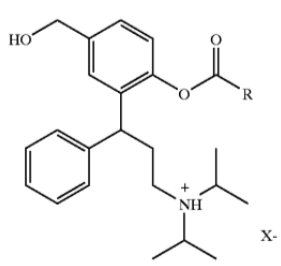
1. Nature and Stage of Proceedings

This is a Hatch-Waxman patent infringement litigation. Plaintiffs Pfizer Inc. and UCB Pharma GmbH (collectively, "Plaintiffs") sued eleven generic pharmaceutical manufacturers ("Defendants") for infringement of U.S. Patent Nos. 6,858,650 ("the '650 patent"), 7,384,980 ("the '980 patent"), 7,855,230 ("the '230 patent"), 7,985,772 ("the '772 patent"), and 8,338,478 ("the '478 patent") (collectively, the "patents-in-suit") because each Defendant filed an Abbreviated New Drug Application to manufacture and sell Plaintiffs' drug product Toviaz®, which is indicated for the treatment of overactive bladder. The parties filed a Joint Claim Chart on July 1, 2014 (D.I. 97), which sets forth the disputed claim terms and proposed constructions. Two claim terms, one each from the '650 and '980 patents, are in dispute, and both were proposed as requiring construction at Defendants' behest. The two disputed claim "terms" are:

- Term 1 (which is in fact the entirety of claim 1 of the '650 patent):

  Compounds of general formula I:

  Formula I

  in which R denotes C_1-C_6-alkyl, C_3-C_{10}-cycloalkyl, substituted or unsubstituted phenyl and X^- is the acid residue of a physiologically compatible inorganic or organic acid.

- Term 2 (claim 4 of the '980 patent):

  contact of the muscarinic receptor

There are no disputed terms among the claims of the other three patents-in-suit.[1]

[1] The parties agreed that the term "effective amount" in all asserted claims of the patents-in-suit should be construed as "an amount sufficient to achieve a desired result." The

2. Summary of Argument

Defendants seek to re-write the entirety of independent claim 1 of the '650 patent under the guise of claim construction. Claim 1 of the '650 patent is a simple, straightforward claim to a genus of chemical compounds. More specifically, it is a claim to certain salt forms of these compounds. These claimed compounds are limited by their chemical structure, and nothing more. Defendants seek to convert claim 1 of the '650 patent – a product claim on its face – into a product-by-process claim by requiring that "the compounds of the claims of the '650 patent are limited to those obtained" by a particular method of making these compounds. *See* §5.1, *infra.* Defendants' proposal comes in spite of the fact that the very manufacturing process they seek to import into claim 1 is already separately claimed in the same '650 patent (in unasserted claim 7). Defendants point to no word or phrase in claim 1 to support converting this product claim into a product-by-process claim, nor can they. There is no support in the intrinsic record that the claims should be so limited, and the controlling legal authority, including that of this Court, prohibits the construction of product claims in this manner.

"Contact of the muscarinic receptor" in claim 4 of the '980 patent is the other claim term in dispute. It is also entitled to its plain and ordinary meaning. The real dispute between the parties concerns only the term "contact." This plain English word is not specially treated in the intrinsic record. There is accordingly no basis to narrow the term "contact" to mean "binding," as Defendants propose.

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term appears in the following claims: claims 3-7 and 10-16 of the '980 patent, claims 1-5 of the '230 patent, claims 4 and 6-8 of the '772 patent, claims 6-8 and 10-12 of the '478 patent, and claims 21-24 of the '650 patent. Plaintiffs respectfully request that the Court adopt the agreed-upon construction.

3. Pertinent Background

The patents-in-suit describe and claim chemical compounds, more particularly novel derivatives of the class of compounds known as 3,3-diphenylpropylamines. In addition, the patents claim salt forms of these compounds, methods of manufacturing the compounds and their salt forms, pharmaceutical compositions comprising one of the claimed derivatives, and methods of treatment through administration of that claimed derivative. The '980 patent describes and claims certain of these compounds, including the compound fesoterodine. The '650 patent is directed to, and claims, specific salt forms of these compounds, including fesoterodine fumarate.

The specification of the '650 patent differs from that of the '980 patent and the other three patents-in-suit (collectively with the '980 patent, the "Compound Patents"), which share a common specification and a common parent application, PCT/EP99/03212. The '650 patent is titled "Stable Salts of Novel Derivatives of 3,3-Diphenylpropylamines." *See* '650 patent (J.A. 1). The Compound Patents are all titled "Derivatives of 3,3-Diphenylpropylamines." *See, e.g.,* '980 patent (J.A. 2). The '650 patent "concerns highly pure, crystalline, stable compounds of novel derivatives of 3,3-diphenypropylamines in the form of their salts, a method for manufacturing these and highly pure, stable, intermediate products." '650 at col. 1, ll. 10-14. The Compound Patents disclose the novel derivatives of 3,3-diphenylpropylamines that are referenced in the '650 patent. *Id.* at col. 1, ll. 15-16 ("[f]rom document PCT/EP99/03212 novel derivatives of 3,3-diphenylpropylamines are known.") These novel derivatives "are valuable prodrug[s] for the treatment of urinary incontinence and other spasmodic complaints." *Id.* at col. 1, ll. 17-18. The '980 patent provides that these "novel prodrugs of antimuscarinic agents [have] superior pharmacokinetic properties compared to present drugs [such] as oxybutynin and tolterodine." '980 at col. 2, ll. 19-22.

The ’650 patent describes that one of the two “[p]referred compounds of the present invention” is R-(+)-2-(3-diisopropylamino-1-phenylproyl)-4-hydroxymethylphenylisobutyrate ester hydrogen fumarate. ‘650 at col. 3, ll. 39-41. This compound is the fumarate salt form of fesoterodine. Fesoterodine fumarate is the accused product in this case and is the active ingredient in Plaintiffs’ drug, Toviaz®.

The ’650 patent describes – separately – a reaction process used to synthesize fesoterodine fumarate. *See, e.g.,* ’650 at col. 4, l. 20 - col. 6, l. 22 (describing methods for manufacturing the claimed compounds) and col. 13, l. 31 - col. 17, l. 25 (describing the patent’s “Embodiments”). This reaction process is shown schematically in Figure 1. The patent provides that the reaction process “is explained using reaction diagram 1, (*see* ’650 patent, **FIG. 1**), in which the conversions with R-configured compounds are described, ***but without this being restrictive***.” *Id.* at col. 9, ll. 25-27 (emphasis added). This is the reaction process that Defendants seek to import into claim 1 of the ’650 patent.

Distinct independent and dependent claims to the reaction process exist separate and apart from claim 1 in the ’650 patent. There are three sets of claims: claims 1-6 claim compounds, claims 7-20 claim methods of manufacturing the compounds, and claims 21-24 claim methods of treatment using the compounds. *In the first set of claims*, claim 1 recites a genus of compounds defined by the chemical structure of “general formula I.” *Id.* at col. 23, ll. 15-32. Claims 2-6 depend on claim 1 and each claim a subset of the compounds claimed by claim 1. *In the second set of claims*, claim 7 is an independent claim to a method of manufacturing compounds of general formula I. *See id.* at col. 24, l. 28 - col. 26, l. 17. The method of manufacturing of claim 7 is the reaction process that Defendants propose claim 1 be construed to include. *Id.* Claims 8-20 depend from claim 7, and also claim methods of

manufacturing. *In the third set of claims*, claims 21-24 depend from claim 1 and claim methods of treating urinary incontinence by administering an effective amount of the claimed compound(s).

4. Claim Construction Principles

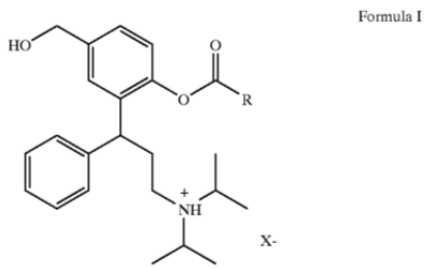
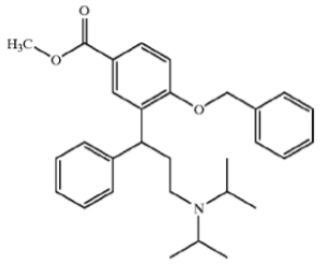
Interpreting claim language is not always difficult— it often "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*). General descriptive terms will ordinarily be given their full meaning; modifiers will not be added to broad terms standing alone. *Johnson Worldwide Associates, Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). In construing claims, "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entertainment Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) *citing Phillips*, 415 F.3d at 1313.

With respect to "product claims[,] the article is defined in terms of structural characteristics only." *Biacore, AB v. Thermo Bioanalysis Corp.*, 79 F.Supp.2d 422, 456 (Robinson, J.) (D. Del. 1999) (citing *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 997 (Fed. Cir. 1993)). Differently, a product-by-process claim is "one in which the product is defined at least in part in terms of the method or process by which it is made." *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 842 (Fed. Cir. 1992) (citations omitted); *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158, n.* (1989). In contrast to product claims,

"[p]roduct-by-process claims are characterized as being devoid of significant structural description of the final article, instead relying, at least in part, on a description of 'the process used to obtain [the claimed invention]' to define it." *Biacore*, 79 F.Supp.2d at 456 (citing *Mentor*, 998 F.2d at 997).

5. Argument

5.1 Claim 1 of the '650 Patent Is a Compound Claim and Should Be Construed Accordingly

Term for Construction	Plaintiffs' Construction	Defendants' Construction
Compounds of general formula I  Formula I in which R denotes C_1-C_6-alkyl, C_3-C_{10}-cycloalkyl, substituted or unsubstituted phenyl and X^- is the acid residue of a physiologically compatible inorganic or organic acid.	Plain meaning.	The compounds of the claims of the '650 patent are limited to those obtained by the "crucial" reaction process of the specification wherein the intermediate compound of Formula III is (1)  Formula III subjected to hydrogenation followed by reduction, or vice versa, and (2) the resulting product is treated with an acylation agent.

Defendants seek to re-write claim 1 as a product-by-process claim that requires the use of a particular reaction process to obtain the claimed compounds. There is nothing ambiguous in the language of the claim, and there is no suggestion in the intrinsic record that it be accorded any special construction. On its face, the plain meaning of the claim is a genus of compounds limited only by its chemical structure – not the method of its making. "The method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. … A novel product that meets the criteria of patentability

is not limited to the process by which it was made." *Vanguard Products Corp. v. Parker Hannifan Corp.*, 234 F.3d 1370, 1372-73 (Fed. Cir. 2000); *see also Outlast Tech., Inc. v. Frisby Tech., Inc.*, 128 Fed. App'x. 122, 127, 2005 WL 712452, at *4, n. 4 (Fed. Cir. 2005) ("absent clear and unambiguous evidence to the contrary, a product claim is not limited to, or does not exclude, products made by a particular process.")

(a) The Language of Claim 1 Supports a Plain Meaning Construction

Claims are interpreted through the lens of a person of ordinary skill in the art, but even a person with the most basic understanding of organic chemistry would understand the meaning of claim 1 of the '650 patent to be plain and unambiguous. On its face, claim 1 is to a genus of compounds "of general formula I," which is identified in the claim by its chemical structure, along with a series of substitutions ("substituents") that may be substituted in the open positions of Formula I denoted by "R" and "X-." '650 at col. 23, ll. 15-32. The claim is that simple.

It is straightforward that claim 1 is a product claim: it is "defined in terms of structural characteristics only." *Biacore*, 79 F.Supp.2d at 456. Defendants suggest in their proposed construction that the process exemplified in the '650 specification for synthesizing the compounds of claim 1 is deemed "crucial." That is a misreading of the disclosure, where the word "crucial" bears no connection to the claimed compounds themselves. Even were that not the case, moreover, it is black-letter patent law that "[t]he claims, not specification embodiments, define the scope of patent protection." *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009). The appropriate question is whether there is anything in the language of ***the claim*** that would suggest to the skilled artisan that the inventor intended to limit the scope of the claimed salt compounds to a manner in which they can be made. Because the only "language" in a claim consists of a core chemical structure and possible substituent groups, it is clear that no process limitation should be imported.

Indeed, this Court has undertaken the very analysis that controls here and has articulated a list of commonly-used claim language that might trigger the construction of a product claim as a product-by-process claim. *See Biacore,* 79 F.Supp.2d at 456 ("Typically, it is the wording of the claim which indicates that it is a product-by-process claim. For example, product-by-process claims employ terms such as 'prepared in accordance with,' 'by the process of,' whereby, 'product of the process,' 'resulting from the process of,' and 'being produced by the process comprising.'") No such term, nor any language even remotely similar, appears in claim 1.

Defendants do not even identify a specific ***term*** of claim 1 as suggestive of a process limitation – instead, they seek reconstruction of the entirety of claim 1. This underscores the absence of any real ambiguity in the claim because by advancing a wholesale re-write, Defendants essentially take the position that the entire claim is so ambiguous that none of its language would be understood by one of ordinary skill. Even where process-limiting language arguably appears in a patent claim, both this Court and the Federal Circuit nonetheless have repeatedly refused to convert a product claim to a product-by-process claim on claim construction. *See, e.g., Vanguard*, 234 F.3d at 1372 (considering but rejecting "integral" as converting a product claim to a product-by-process claim); *Outlast*, 128 Fed. App'x. at 126-127 (considering but rejecting that prosecution statements limited "on the surface of said base material" to a particular process); *Biacore*, 79 F.Supp.2d at 456 (construing "which is bound" and "activated to contain"); *In re Rosuvastatin Calcium Patent Litigation*, 2009 WL 1220542, at *6-7 (D. Del. 2009), *Report and Recommendation Adopted by* 2009 WL 3378602 (D. Del. 2009) (construing "in the form of"). Because no such process-implying term appears in claim 1 of the '650 patent, Defendants' proposed construction is even further removed from constructions rejected in other decisions that arguably featured such language in the claim at-issue.

(b) Neither the Patent Specification Nor the Prosecution History Define the Scope of the Claim Nor Disavow Any Subject Matter from the Claim

There is nothing in the '650 patent specification to indicate that the inventor sought to limit his invention to a particular reaction process. *Phillips*, 415 F.3d at 1315 ("claims must be read in view of the specification, of which they are a part"). To the contrary, the '650 patent first discloses "highly pure, crystalline, stable compounds of novel derivatives of 3,3-diphenypropylamines in the form of their salts…," and then lists methods for manufacturing these products as a ***separate*** category of subject matter. '650 at col. 1, ll. 10-14. The patent further discloses that "the problem for the present invention is therefore to provide highly pure, crystalline, stable compounds of novel derivatives of 3,3-diphenylpropylamines in the form of their salts," and then identifies methods of manufacturing to address "[a] ***further*** problem." *Id.* at col. 2, ll. 17-26. These statements express a clear understanding that the compounds and the reaction processes are separately patentable subject matter. The claims are consistent with this understanding, as the first set of claims (claims 1-6) claim compounds, and the second set of claims (claims 7-20) claim a method of manufacturing the claimed compounds. Defendants' attempt to blur the patentable distinction between claims 1-6 and 7-20 directly conflicts with the specification's delineation of ***both*** products and methods to make these products as separate categories of novel subject matter.

Where the '650 patent specification describes the reaction process of Defendants' proposed construction, the inventor consistently explains that the claimed invention is not limited to only this reaction process. When the reaction process is first disclosed, the patent provides that the reaction process is a further invention in addition to the compounds themselves. '650 at col. 4, ll. 20-22 ("The present invention ***also*** includes methods for manufacturing the compounds in accordance with ***the invention*** of general formula I…") (emphases added). The patent then

provides that the reaction process "is explained using reaction diagram 1 (see **FIG. 1**), in which the conversions with R-configured compounds are described, ***but without this being restrictive***." *Id.* at col. 9, ll. 25-27 (emphasis added). With or without this non-limiting language, reflecting a non-limiting intent, the law is clear that preferred embodiments, such as the reaction process disclosed in the '650 patent, do not limit claims. *Libel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904-909, 913 (Fed. Cir. 2004) ("it is improper to read limitations from a preferred embodiment described in the specification - even if it is the only embodiment - into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited"); *Kara Tech*, 582 F.3d at 1348. As such, this process should not be read into the claim. *Outlast*, 2005 WL 712452 at *4, n. 4 ("absent clear and unambiguous evidence to the contrary, a product claim is not limited to, or does not exclude, products made by a particular process.")

Additionally, although a patent's prosecution history may evidence the proper construction of a claim term, (*see Phillips*, 415 F.3d at 1317), neither the Examiner nor the patent applicants made any statement during prosecution of the '650 patent that would suggest claim 1 must be limited to any particular reaction process. Defendants evidently concede as much, as they identify no portion of the '650 prosecution history in the Joint Claim Chart submitted to this Court. *See* D.I. 97.

In sum, the plain reading of claim 1 of the '650 patent requires that the claim be construed according to its plain meaning as a product claim. There is no indication in the claims, the specification, or the prosecution history that the claim should be limited to only compounds obtained as a result of a particular process, and claim 1 should be construed accordingly. *Outlast*, 2005 WL 712452 at *4, n. 4.

(c) Defendants' Proposed Construction Renders Claims of the '650 Patent Prohibitively Superfluous and Nonsensical

Defendants' proposed construction also fails under the doctrine of claim differentiation. *Evonik Degussa GmbH v. Materia Inc.*, 2013 WL 5780414, at *10-12 (D. Del. 2013) (reviewing recent precedent related to the proposition that "it is a general rule in claim construction disputes that courts should not construe a term in one claim in a manner that would render its use in another claim redundant or superfluous" and "find[ing] that [independent] Claim 8 would essentially be superfluous to and redundant of [independent] Claim 1 if it were to adopt Defendants' proffered construction…"). Adoption of Defendants' proposal would render other claims of the '650 patent not just "redundant or superfluous," but in several instances, nonsensical and/or inoperable.

Defendants proposed construction for claim 1 reads: "The compounds of ***the claims of the '650 patent*** are limited…." As a preliminary matter, Defendants' construction of claim 1, on its face, is not just limited to the salt compounds of claim 1, but would limit every claim of the '650 patent. This is nonsensical.

Defendants' construction reads a series of method steps into claim 1 that, for infringement purposes, effectively converts that product claim into a method of manufacturing claim defined by the reaction process. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (*en banc*) ("this court now restates that 'process terms in product-by-process claims serve as limitations in determining infringement'" (citing *Atlantic Thermoplastics,* 970 F.2d at 846-47)). But claim 7 expressly claims the method of manufacturing the compounds ***of claim 1*** separate and apart from claim 1 and tracks the same reaction process that Defendants seek to import into claim 1. In other words, the method of manufacturing claimed in claim 7 of the '650 patent would have no distinct meaning from claim 1 if Defendants' proposed construction of

claim 1 is adopted – both claims would cover the same process of making the same compounds. Defendants' proposed construction of claim 1 thus renders claim 7 superfluous and should be rejected. *Vanguard*, 234 F.3d at 1372 (affirming district court's refusal to read a process limitation into a product claim where process was separately claimed in patent).

Focusing on the impact of Defendants' proposed construction on claim 1 alone, the construction is flawed for an additional reason: it leaves the claim itself nonsensical and inconsistent with the inventor's clear intent with respect to the claimed subject matter. Defendants' proposed construction tracks the reaction process disclosed in the '650 patent, (*see, e.g.,* col. 4, l. 26 - col. 6, l. 22), with the important exception that the construction ignores the final step, "step (d)," of the process described. Steps (a) – (c) of the disclosed process result in compounds that are not in salt form. Step (d) of the process described in the specification – but absent from Defendants' construction – is the step in the synthesis process that puts the subject compounds into salt form. All four steps, steps (a) - (d), disclosed in the process described in the '650 specification are thus necessary to obtain compounds in a salt form. The '650 patent is titled and clearly directed to "Stable Salts of Novel Derivatives of 3,3-diphenylpropylamines," and claim 1 is directed to "compounds of general formula 1," which are salt forms (*see, e.g.* '650 at col. 2, ll. 33-47 ("highly pure, crystalline, stable compounds of the 3,3-diphenylpropylamines ***in the form of their salts with general formula I*** are provided….") (emphasis added)). Yet execution of the reaction process without the fourth step, as Defendants propose, would not result in the compounds of claim 1. Put simply, claim 1 is to a genus of salts, and adoption of Defendants' proposed construction would eviscerate that subject matter. For this reason alone, Defendants' construction must be rejected.

5.2 There is No Basis in the Intrinsic Record to Limit Claim 4 of the '980 Patent to "Binding to the Muscarinic Receptor"

Term for Construction	Plaintiffs' Construction	Defendants' Construction
contact of the muscarinic receptor	Plain meaning.	binding to the muscarinic receptor

The term "contact of the muscarinic receptor' is entitled to its plain meaning. The real dispute between the parties here is over the term "contact." This plain English term is entitled to its plain English meaning, which is unambiguous in the context of the claim as it would be read by a person of ordinary skill in the art. Nothing in the intrinsic record suggests otherwise.

Claim 4 of the '980 patent, in its entirety, reads as follows:

> **4.** A method of ***antagonizing*** a muscarinic receptor in a patient in need thereof, the method comprising administering to the patient R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester or a salt thereof with a physiologically acceptable acid so as to result in ***contact of the muscarinic receptor*** with an effective amount of R-(+)-2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenol.

'980 at col. 56, ll. 38-46 (emphases added). There are no ambiguities in this claim. The compound "R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester" is also known as fesoterodine. The compound "R(+)-2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenol" is also known as 5-hydroxymethyl tolterodine, or "5-HMT." Fesoterodine metabolizes into, and is a "prodrug" of, 5-HMT, which is a compound that acts at the receptor level to effect the treatment for which Toviaz® is prescribed. Where claim 4 claims a method of "antagonizing" (i.e., blocking) a muscarinic receptor in a patient by administering fesoterodine, or a salt thereof, the result is necessarily some "contact" of the muscarinic receptor by an amount of 5-HMT effective to antagonize the muscarinic receptor. Because 5-HMT was known by the priority date of the '980 patent to target

muscarinic mechanisms, and thus muscarinic receptors, upon administration of fesoterodine, one of ordinary skill in the art would expect 5-HMT to contact the muscarinic receptor. *Id.* at col. 23, ll. 45-48. This is plain and only logical: without contact, it would not be possible to "antagonize a muscarinic receptor in a patient," as the claim requires and the patent describes.

Defendants seek to replace the term "contact" with "binding" in claim 4 of the '980 patent. There is no justification for this replacement which would narrow the scope of claim 4 to require some specific form of "contact" with the receptor. Not surprisingly, given its plain English meaning, the '980 patent does not address or define – much less assign some unconventional or special meaning to – the term "contact." Nor was the term given a narrower meaning, as "binding" or otherwise, during the prosecution history of the '980 patent. There is no support for Defendants' construction.

6. Conclusion

For the above reasons, Plaintiffs respectfully request that the Court construe the claims in the manner proposed by Plaintiffs and, for the undisputed term, as agreed by the parties.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Pfizer Inc. and UCB Pharma GmbH

OF COUNSEL:

Dimitrios T. Drivas
Jeffrey J. Oelke
James S. Trainor, Jr.
Robert Counihan
Ryan P. Johnson
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200

July 31, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 31, 2014, upon the following in the manner indicated:

John W. Shaw, Esquire — *VIA ELECTRONIC MAIL*
Jeffrey T. Castellano, Esquire
Andrew E. Russell, Esquire
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
Attorneys for Alkem Laboratories Ltd.

A. Neal Seth, Esquire — *VIA ELECTRONIC MAIL*
Lawrence M. Sung, Esquire
Rachel K. Hunnicutt, Esquire
WILEY REIN LLP
1776 K Street, NW
Washington, DC 20006
Attorneys for Alkem Laboratories Ltd.

Adam W. Poff , Esquire — *VIA ELECTRONIC MAIL*
Pilar G. Kraman, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801
Attorneys for Sandoz Inc.

Thomas P. Steindler, Esquire — *VIA ELECTRONIC MAIL*
MCDERMOTT WILL & EMERY LLP
600 13th Street N.W.
Washington, D.C. 20005
Attorneys for Sandoz Inc.

Katherine Nicole Clouse, Esquire — *VIA ELECTRONIC MAIL*
MCDERMOTT WILL & EMERY LLP
28 State Street
Boston, MA 02109
Attorneys for Sandoz Inc.

Krista Vink Venegas, Esquire — *VIA ELECTRONIC MAIL*
MCDERMOTT WILL & EMERY LLP
227 West Monroe Street
Chicago, IL 60606
Attorneys for Sandoz Inc.

John C. Phillips, Jr., Esquire — *VIA ELECTRONIC MAIL*
Megan C. Haney, Esquire
PHILLIPS, GOLDMAN & SPENCE, P.A.
1200 North Broom Street
Wilmington, DE 19806-4204
Attorneys for Lupin Ltd.

Robert F. Green, Esquire — *VIA ELECTRONIC MAIL*
Christopher T. Griffith, Esquire
Jessica M. Tyrus, Esquire
Elizabeth M. Crompton, Esquire
Jamaica P. Szeliga, Esquire
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza
180 North Stetson Avenue, Suite 4900
Chicago, IL 60601-6730
Attorneys for Lupin Ltd.

Dominick T. Gattuso, Esquire — *VIA ELECTRONIC MAIL*
PROCTOR HEYMAN LLP
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
Attorneys for Zydus Pharmaceuticals (USA), Inc.

Steven J. Moore, Esquire — *VIA ELECTRONIC MAIL*
James M. Moriarty
KELLEY DRYE & WARREN LLP
400 Atlantic Street
Stamford, CT 06901
Attorneys for Zydus Pharmaceuticals (USA), Inc.

Kelly E. Farnan, Esquire
Anthony Flynn, Jr., Esquire
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
Attorneys for Accord Healthcare Inc., USA and Amneal Pharmaceuticals, LLC

VIA ELECTRONIC MAIL

Michael R. Dzwonczyk, Esquire
Renita Rathinam, Esquire
SUGHRUE MION, PLLC
2100 Pennsylvania Avenue, N.W., Suite 800
Washington, DC 20037
Attorneys for Accord Healthcare Inc., USA and Amneal Pharmaceuticals, LLC

VIA ELECTRONIC MAIL

J. Clayton Athey, Esquire
PRICKETT, JONES & ELLIOTT, P.A.
1310 King Street
Wilmington, DE 19801
Attorneys for Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd.

VIA ELECTRONIC MAIL

Gabriela Materassi, Esquire
Christopher Casieri, Esquire
MCNEELY, HARE & WAR LLP
12 Roszel Road, Suite C104
Princeton, NJ 08540
Attorneys for Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd.

VIA ELECTRONIC MAIL

William D. Hare, Esquire
MCNEELY, HARE & WAR LLP
5335 Wisconsin Avenue, NW, Suite 440
Washington, DC 20015
Attorneys for Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd.

VIA ELECTRONIC MAIL

Collins J. Seitz, Jr., Esquire — *VIA ELECTRONIC MAIL*
Benjamin J. Schladweiler, Esquire
SEITZ ROSS ARONSTAM & MORITZ LLP
100 South West Street, Suite 400
Wilmington, DE 19801
Attorneys for Wockhardt Bio AG and Wockhardt USA, LLC

Joseph M. Reisman, Ph.D. — *VIA ELECTRONIC MAIL*
KNOBBE, MARTENS, OLSON & BEAR, LLP
12790 El Camino Real
San Diego, CA 92130
Attorneys for Wockhardt Bio AG and Wockhardt USA, LLC

Jay R. Deshmukh, Esquire — *VIA ELECTRONIC MAIL*
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue N.W., Suite 900
Washington, DC 20006
Attorneys for Wockhardt Bio AG and Wockhardt USA, LLC

Sheila N. Swaroop, Esquire — *VIA ELECTRONIC MAIL*
Thomas P. Krzeminski, Esquire
Karen M. Cassidy, Esquire
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Attorneys for Wockhardt Bio AG and Wockhardt USA, LLC

Mary B. Matterer, Esquire — *VIA ELECTRONIC MAIL*
Richard K. Herrmann, Esquire
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801-1494
Attorneys for Impax Laboratories, Inc.

Phillip B. Philbin, Esquire
C. Kyle Musgrove, Esquire
Scott Cunning, Esquire
Sarah Hasford, Esquire
HAYNES AND BOONE LLP
800 17th Street, NW, Suite 500
Washington, DC 20006
Attorneys for Impax Laboratories, Inc.

VIA ELECTRONIC MAIL

John M. Seaman, Esquire
ABRAMS & BAYLISS LLP
20 Montchanin Road, Suite 200
Wilmington, DE 19807
Attorneys for Hetero USA Inc. and Hetero Labs Limited

VIA ELECTRONIC MAIL

Chad A. Landmon, Esquire
Matthew S. Murphy, Esquire
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103
Attorneys for Hetero USA Inc. and Hetero Labs Limited

VIA ELECTRONIC MAIL

Delphine W. Knight Brown, Esquire
AXINN, VELTROP & HARKRIDER LLP
114 West 47th Street
New York, NY 10036
Attorneys for Hetero USA Inc. and Hetero Labs Limited

VIA ELECTRONIC MAIL

Richard L. Horwitz, Esquire
David E. Moore, Esquire
Bindu A. Palapura, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
Wilmington, DE 19801
Attorneys for Apotex Inc.

VIA ELECTRONIC MAIL

William A. Rakoczy, Esquire
Paul J. Molino, Esquire
Anuj K. Wadhwa, Esquire
Kevin P. Burke, Esquire
Erin M. Forbes, Esquire
Heinz J. Salmen, Esquire
Damon Gupta, Esquire
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
Six Hubbard Street, Suite 500
Chicago, IL 60654
Attorneys for Apotex Inc.

VIA ELECTRONIC MAIL

/s/ Maryellen Noreika

Maryellen Noreika (#3208)